a shaft extending from a proximal end portion to a distal end portion; and

a distal tip section at said distal end portion of said shaft;

said shaft and said distal tip section comprising fluorinated ethylene propylene and being joined by a thermal bond, said distal tip section containing between about 20% and 75% by weight of a radiopaque material selected from the group consisting of tungsten, titanium, tantalum, platinum, gold, silver, bismuth trioxide and lead, and

said shaft being distinctly less radiopaque than said distal section.

14. (amended) An introducer sheath comprising:

a shaft extending from a proximal end to a distal end; and

a distal tip section at said distal end of said shaft,

said shaft and said distal tip section comprising fluorinated ethylene propylene, said distal tip section containing radiopaque particles, said shaft being distinctly less radiopaque than said distal tip section,

said distal tip section contains between about 50% and 55% by weight of tungsten particles that range in size from about 1.4 microns to about 1.8 microns.

REMARKS

This Preliminary Amendment is filed along with a Request for Continued Examination (RCE). A final rejection was previously mailed on March 26, 2003.

Claims 1, 2, 4, 10, 13 and 16 stand rejected under 35 U.S.C. §103(a) as being unpatentable over Parker (270) in view of Jansen. Claims 14 and 15 stand rejected under 35 U.S.C. §103(a) as being unpatentable over Parker (270) in view of Hopkins and Jansen. Claims 5, 6, 11 and 12 stand rejected under 35 U.S.C. §103(a) as being unpatentable over Parker (170) in view of Jansen as applied to claims 1, 2, 4, 10, 13 and 16, and further in view of Hopkins. Claim 15 has been cancelled herein and its limitation has been incorporated into claim 14. Claim 16 has been cancelled herein and its limitation has been added to claim 1.

The present application is directed to an introducer sheath that comprises a shaft having a short distal tip section bonded thereto. The distal tip section is considerably more radiopaque than the shaft. As claimed in claim 1, both the shaft and the distal tip section of the introducer sheath are made of fluorinated ethylene propylene (FEP), and the sections are

joined by a thermal bond. The distal tip contains between about 20% and 75% by weight of a specified radiopaque material.

It is desirable for an introducer sheath to be formed of a polymeric material that has sufficient radial rigidity to remain open upon removal of the dilator, but that is also sufficiently flexible to permit manipulation without kinking under conditions of normal use. In addition, by forming the shaft and the distal tip section of the same or a similar polymer, the sections are amenable to formation of a reliable bond between them, such as a thermal bond. The existence of a reliable bond between the shaft and the distal tip section allows the sheath to flex as it passes through tortuous bodily passageways with a decreased likelihood of disengagement of the small distal tip section from the shaft.

A problem has existed in the art regarding the satisfactory bonding of a short, highly loaded radiopaque tip to the shaft of the introducer sheath. It is known in the art to provide an introducer sheath with a separate flexible soft distal tip portion that is bonded to the distal end of a sheath formed of a harder material. Such soft distal tip portions are generally made of copolymers that can be substantially loaded with radiopaque materials such as tungsten or barium, while the rest of the introducer adjacent to the distal tip portion contains substantially less radiopaque material. Copolymers, however, have a higher coefficient of friction than is desirable in an introducer sheath. It is more desirable to utilize a material such as FEP that has a low coefficient of friction, so that catheters and other interventional devices can pass through the sheath with a minimum of resistance. It is also desirable that the low friction material be amenable to high loadings of radiopaque material, and yet be able to maintain good flexibility and kink resistance. Furthermore, the low friction material should be of a type that is capable of forming a reliable bond with the main body of the sheath material. The present inventors have addressed this need by utilizing FEP as the shaft material and the material of the distal tip.

The bond zone between the distal tip and the sheath material is an area of very high stress because it is at or very near the area that gets the most bending forces. Relatively large differences in material properties across such a short bond zone further concentrates the stresses in the bond zone, making the bond susceptible to failure. Since the sheath is usually placed in an artery, the separation of a short tip segment from the remainder of the sheath would result in a dangerous embolus free floating in the arterial system. The embolus would eventually lodge somewhere and occlude blood flow to tissue. The use of FEP as both the

shaft and distal tip sections enables the formation of a reliable bond to reduce the chance of failure, and also enable the distal tip to be formed of an extrudable material that is susceptible to high loadings of radiopaque material.

The use of FEP as the material to form both the shaft and the distal section enables these sections to be thermally bonded such that a good molecular mix of molten materials may be obtained. The highly loaded tip material does not readily flow into and mix with the sheath material during the bonding process because of the high percentage of filler material in the tip. Frequently, the interface between prior art materials at the bond site is a "cold" bond or adhesive connection. Although such a connection may initially appear to provide a strong weld or bond, it is in fact much weaker than desired. When the sheath components are formed of FEP, a particularly reliable bond can be formed. The material in the bond zone melts during thermal bonding as the sheath and tip move together, thereby causing a shearing of the molten material at the interface. This shearing action forces the highly loaded tip material to blend or mix with the sheath material. The overall result is a true molecular mixing or weld between the two materials. The highly radiopaque tip becomes an integral part of the sheath, and yet enables the operator to radiographically distinguish the exact distal end of the sheath.

The Examiner has recognized that the Parker reference does not teach FEP as either a shaft or distal tip material. The secondary Jansen reference discloses the use of FEP as a tubing material for a reinforced catheter. FEP is disclosed as an alternative material (along with numerous others) for inner liner 202 (Col. 9, lines 35-43) and proximal outer section 218. Proximal outer section 218 is disclosed to be a section of lesser flexibility. This segment is then coupled with more flexible distal segments 212, 214, 216 that are formed of other compositions. According to Jansen, if a more flexible section is required, the outer tubing member may be made of polymers of suitable softness and flexibility, such as polyurethane, LDPE, PVC and THV. Col. 11, lines 55-58. Thus, rather than teaching or suggesting the use of FEP as a satisfactory material for the distal section of an introducer sheath, Jansen actually teaches away from the use of FEP as a distal tip material in favor of the other materials recited above.

One skilled in the art searching for a solution to the problem of forming an introducer sheath having a highly radiopaque distal tip bonded to a shaft in a manner such that the resulting sheath has a flexibility similar to that of the shaft would not find the solution to this

problem in the cited combination of references. Rather, one would conclude from the Jansen reference that FEP was not a desirable material for forming a distal tip material. In addition to the foregoing, the Jansen reference does not disclose a sheath having a distal tip portion having high loadings of radiopaque markers, nor does it even discuss the difficulty in attaining high loadings with FEP.

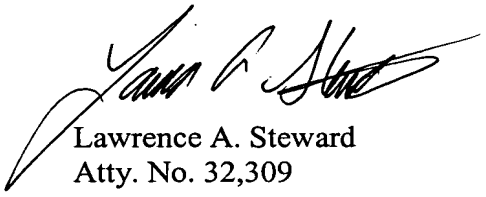
Thus, for the reasons provided above, Applicants submit that claim 1 and dependent claims 2, 4, 10 and 13 are allowable over Parker (270) in view of Jansen.

Claim 14 stands rejected under 35 U.S.C. §103(a) as being unpatentable over Parker (270) in view of Hopkins and Jansen, and claims 5, 6, 11 and 12 stand rejected under 35 U.S.C. §103(a) as being unpatentable over Parker (170) in view of Jansen as applied to claims 1, 2, 4, 10, 13 and 16, and further in view of Hopkins. Parker (270) and Jansen have been discussed above. The Hopkins reference was cited for teaching the use of radiopaque materials such as tungsten in a catheter, and for teaching that particles can be as small as 0.9 microns, which, according to the Examiner, suggests that they can be any size larger than 0.9. The Hopkins patent is directed to a compliant marker band that is heat shrunk over a catheter or sheath, thus eliminating the need for heat or adhesive bonding. Col. 2, lines 34-36; Col. 3, lines 15-17. The marker band surrounds the external surface of the catheter or sheath and includes a radiopaque material such as tungsten.

By using a marker band, Hopkins teaches away from the present invention by employing technology that the present inventors desire to avoid. The use of a marker band that is heat shrunk or otherwise positioned over a sheath increases the thickness of the sheath wall, and thereby imparts an element of rigidity to the sheath. In addition, the use of a marker band forces the operator to estimate the exact location of the distal tip of the device. In the present invention, the radiopaque marker is the distal tip, thereby eliminating this guesswork. Applicants do not dispute that highly radiopaque marker bands are known in the art. However, the Hopkins reference does not teach or suggest the use of FEP in an introducer sheath for the purposes described, nor does it teach or suggest that a distal tip can function as a radiopaque marker. In addition to the foregoing, one skilled in the art would not likely make the cited combination, since Hopkins also teaches away from a purpose of the present invention, namely the use of a highly loaded distal tip, instead of a marker band. Thus, Applicants respectfully submit that claims 5, 6, 11, 12 and 14 are allowable in view of the cited combination.

Based upon the remarks provided hereinabove, Applicants respectfully submit that all claims 1, 2, 4-6 and 10-14 are allowable over the combination of references discussed hereinabove. Accordingly, Applicants respectfully request that the Examiner reconsider the previous rejections in view of these claims. If the Examiner believes that prosecution of this application may be expedited by way of a telephone conversation, the Examiner is respectfully invited to telephone the undersigned attorney.

Respectfully submitted,



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MARKED UP COPY OF CLAIMS:

1. (twice amended) An introducer sheath comprising:

a shaft extending from a proximal end portion to a distal end portion; and

a distal tip section at said distal end portion of said shaft;

said shaft and said distal tip section comprising fluorinated ethylene propylene and being joined by a thermal bond, said distal tip section containing between about 20% and 75% by weight of a radiopaque material selected from the group consisting of tungsten, titanium, tantalum, platinum, gold, silver, bismuth trioxide and lead, and

said shaft being distinctly less radiopaque than said distal section.

14. (amended) An introducer sheath comprising:

a shaft extending from a proximal end to a distal end; and

a distal tip section at said distal end of said shaft,

said shaft and said distal tip section comprising [a polymeric material] fluorinated ethylene propylene, said distal tip section containing radiopaque particles, said shaft being distinctly less radiopaque than said distal tip section,

said distal tip section [polymeric material is fluorinated ethylene propylene and] contains between about 50% and 55% by weight of tungsten particles that range in size from about 1.4 microns to about 1.8 microns.